

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

MICHAEL SZYMANSKI, and)	
KARI SZYMANSKI, h/w)	
)	
Plaintiffs,)	Case No.: _____
)	
v.)	JURY DEMANDED
)	
WRIGHT MEDICAL GROUP, INC.,)	
a Delaware corporation,)	
WRIGHT MEDICAL TECHNOLOGY, INC.,)	
a Delaware corporation,)	
WRIGHT MEDICAL EUROPE S.A.,)	
a foreign corporation,)	
JOHN DOE INDIVIDUALS (1-5), and)	
JOHN DOE CORPORATIONS (6-10))	
)	
Defendants.)	

COMPLAINT AND JURY DEMAND

Plaintiffs Michael Szymanski and Kari Szymanski, by and through their attorneys, Thomas Anapol, for their Complaint against the defendants state and allege as follows:

PARTIES

1. Plaintiffs Michael Szymanski and Kari Szymanski (“Plaintiffs”) are each citizens of the State of New Jersey, and reside in Mantua, Gloucester County, New Jersey.
2. At all times relevant hereto plaintiffs Michael Szymanski and Kari Szymanski have been and remain husband and wife.

3. Defendant Wright Medical Group, Inc., is a Delaware corporation with its principal place of business at 5677 Airline Road, Arlington, Tennessee 38002, and as such is deemed to be a citizen of the State of Delaware and a citizen of the State of Tennessee.

4. Defendant Wright Medical Technology, Inc., is a Delaware corporation with its principal place of business at 5677 Airline Road, Arlington, Tennessee 38002, and as such is deemed to be a citizen of the State of Delaware and a citizen of the State of Tennessee.

5. Defendant Wright Medical Technology, Inc., is a wholly owned subsidiary of defendant Wright Medical Group, Inc.

6. Defendant Wright Medical Technology, Inc., does business in New Jersey, and is registered to do business in the State of New Jersey.

7. Defendant Wright Medical Europe, S.A., is a foreign corporation with its principal place of business at Rue Pasteur BP 222, 83089 Toulon Cedex 9, France, and as such is a foreign corporation and is not a citizen of the State of New Jersey.

8. Defendant Wright Medical Europe, S.A., is a wholly owned subsidiary of defendant Wright Medical Group, Inc.

9. Defendants John Doe Individuals 1-5 are individuals (fictitious names for individuals or entities whose actual identities are unknown) who to the best of Plaintiffs' knowledge and belief, are and were the owners, agents, subcontractors, employees, servants, designers, manufacturers, assemblers, inspectors, distributors, packagers, and/or others who worked at the direction of, and/or on behalf of, Defendants and/or their

owners, managers, and/or other personnel and whose conduct, actions, inactions, and negligence caused or contributed to cause the plaintiffs' injuries and damages.

10. Defendants John Doe Corporations 6-10 are subsidiaries, sister corporations, holding corporations or other affiliated entities or agents of the other named Defendants, who were responsible for the injuries suffered by Plaintiffs.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different States, and the amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

12. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) and (c), as a substantial part of the events giving rise to this claim occurred in the State of New Jersey.

FACTUAL ALLEGATIONS

General Allegations as to Profemur Modular Necks

13. Plaintiff Michael Szymanski brings this product liability personal injury action as a recipient of a defective medical device, a component of a Wright Medical artificial hip system known as a Wright Medical Profemur titanium alloy (Ti6Al4V) long modular neck (hereinafter "Profemur titanium long modular neck" or "Profemur Ti6Al4V long modular neck"), that was designed, manufactured, labeled, marketed, and distributed by the defendants Wright, and other persons yet to be identified.

14. Defendant Wright Medical Group, Inc., directly or through its aforesaid subsidiaries or affiliates, designed, manufactured, labeled, marketed, promoted,

distributed, and sold in the United States various prosthetic orthopedic devices, including the Profemur titanium long modular neck and the other Wright Medical artificial hip components described herein.

15. Defendant Wright Medical Technologies, Inc., directly or through its aforesaid subsidiaries or affiliates, designed, manufactured, labeled, marketed, promoted, distributed, and sold in the United States the Profemur titanium long modular neck and the other Wright Medical artificial hip components described herein.

16. Defendant Wright Medical Europe, S.A., directly or through its aforesaid subsidiaries or affiliates, designed, manufactured, labeled, marketed, promoted, placed into the stream of commerce and distributed in the United States the Profemur titanium long modular neck component described herein.

17. Wright Medical Technology, Inc., Wright Medical Group, Inc., and Wright Medical Europe, S.A., each monitored the reporting of adverse events related to the Profemur titanium long modular neck and the other Wright Medical artificial hip components described herein, and had a role in the decision process and response of the defendants Wright, if any, related to those adverse events.

18. At all times relevant hereto, each of the defendants Wright were the representatives, agents, employees, joint-venturers, or alter egos of the other and was acting within the scope of its respective authority by virtue of those interrelationships.

19. In December of 1999, Wright acquired a European manufacturer of artificial hip devices known as Cremascoli Ortho, which had designed and manufactured artificial hips with a modular neck component.

20. By way of what is known as the Section 510(k) Premarket Notification Process, on December 13, 2000, Wright received permission from the United States Food and Drug Administration [FDA] to distribute in the United States its first Profemur hip devices.

21. The Profemur hip devices the FDA permitted Wright to distribute by way of the above referred 510(k) process included a modular neck component that had been designed in Europe by Cremascoli.

22. Sometime after December 13, 2000, the defendants Wright began to manufacture, label, market, promote, distribute and sell in the United States the Wright Medical Profemur hip system and its components, including the Profemur modular necks.

23. The Wright Medical Profemur modular necks that were distributed after December 13, 2000, and before August 25, 2009, were all made of a titanium-aluminum-vanadium alloy known as Ti6Al4V.

24. In the year 2000, and in all years thereafter to the present, Ti6Al4V was an alloy generally available for use in manufacturing implantable medical devices.

25. In the year 2000, and in all years thereafter to the present, cobalt-chromium was also an alloy generally available for use in manufacturing implantable medical devices, and in fact was used by the defendants Wright in their manufacturing of certain components for use in Wright Medical artificial hips.

26. The Wright Medical Profemur modular necks, as promoted, marketed, distributed and sold in the United States after December 13, 2000, and before August 25,

2009, for use with various Wright Medical hip systems, were manufactured in twelve models or styles, six of those twelve were generally identified by Wright as “short” necks (i.e. Catalog #s PHA0-1202, PHA0-1212, PHA0-1222, PHA0-1232, PHA0-1242, and PHA0-1252), and six identified by Wright as “long” necks (i.e. Catalog #s PHA0-1204, PHA0-1214, PHA0-1224, PHA0-1234, PHA0-1244, and PHA0-1254).

27. In various marketing and promotional material published and distributed by the defendants Wright from approximately the year 2002, and into the year 2005, and available to surgeons, patients, and the general public, Wright made the following representations, statements, claims and guarantees about its Profemur modular necks:

The modular neck used with the Profemur Hip has been employed by Wright Cremascoli for over 15 years. The necks were designed in 1985 and have been successfully implanted in over 50,000 patients requiring both primary and revision hip procedures. The necks are used in other Wright Cremascoli hip systems besides the Profemur Hip. None of the necks has experienced a clinical failure since their inception. [emphasis added]

And,

The modular neck system, designed by Cremascoli in 1985 (U.S. Patent #4,957,510), has now been successfully implanted in over 50,000 patients requiring both primary and revision hip arthroplasty. Extensive laboratory tests has proven that the coupling between the modular neck and femoral implant guarantees:

- Structural reliability
- Absence of significant micromovement
- Absence of fretting corrosion

[emphasis added]

[Wright Medical Technical Monograph MH688-102 © 2004]

28. In 2001, Wright made a design change to its Profemur modular necks to increase the range of motion that a patient could have in their hip once the device was implanted.

29. In making the 2001 design change to the Profemur modular necks, Wright changed the geometry, weight, and mass of the Profemur modular necks.

30. Thousands of the above referenced modular necks “designed in 1985,” and “successfully implanted in over 50,000 patients,” that Wright claimed, “none of the necks has experienced a clinical failure since their inception,” were of the original design that existed prior to the 2001 design change.

31. In fact, prior to the year 2001 the defendants Wright had received notice of clinical failures in the form of fractures of modular necks that had been implanted in patients in Europe.

32. In its 510(k) Premarket Notification application to distribute its Profemur modular necks in the United States, Wright did not disclose to the FDA that it had notice of clinical failures in the form of fractures of its modular necks that had been implanted in patients in Europe.

33. Once Wright filed its 510(k) Premarket Notification application to distribute its Profemur modular necks in the United States, Wright had a duty to report to the FDA any instances it had notice of, or received notice of, where there was a clinical failure in the form of a fracture of a modular neck that had been implanted in a patient.

34. Once Wright received permission to distribute Profemur modular necks in the United States as a result of its 510(k) Premarket Notification application, Wright had

a duty to report to the FDA any instances it had or received notice of where there was a clinical failure in the form of a fracture of a modular neck that had been implanted in a patient.

35. Prior to January of 2005, Wright had or received notice of clinical failures in the form of fractures of its modular necks that had been implanted in patients in Europe.

36. Prior to April 19, 2005, Wright did not report to the FDA any of the instances it had notice of where it was notified that a Profemur modular neck had clinically failed by the modular neck having fractured in a patient in Europe.

37. On or about April 19, 2005, Wright first reported to the FDA a Profemur modular neck clinical failure where the modular neck implanted in a patient had fractured.

38. After receiving notice of the first modular neck fracture, the Wright defendants received notice of more modular neck clinical failures in the form of fractures of the modular necks.

39. The number of Profemur (Ti6Al4V) modular neck clinical failures in the form of fractures of the modular neck has continued to increase over time, and continues to increase to the present day.

40. The fracture rate for Profemur (Ti6Al4V) long modular necks is approximately eight times the fracture rate of the Profemur (Ti6Al4V) short modular necks.

41. The fracture rate for Profemur (Ti6Al4V) long modular necks implanted in the United States is approximately 1% of the total number of Profemur (Ti6Al4V) long modular necks implanted in the United States.

42. Wright did not inform orthopedic surgeons known to it in the United States to have implanted its hip systems of any reports or concerns about fractures of its Profemur modular necks until a December 1, 2008, "Safety Alert" was sent to certain "medical professionals," where it stated, in part, "[W]e have received reports of 43 modular neck failures as of November 21, 2008. Initial investigations have revealed several commonalities in these failures: heavyweight males, long modular necks, and patient activities such as heavy lifting and impact sports."

43. At the time Wright sent its December 1, 2008 Safety Alert, the Wright defendants in fact were aware of more than 43 modular neck failures (by fracture of the modular neck) as of November 21, 2008, if all of the modular neck fractures of Wright and Cremascoli modular necks that had occurred in patients in Europe had been included in the total.

44. In Wrights' Instructions for Use (IFU) that accompanied these products from their introduction into the United States, through 2008, if not later, Wright contraindicated these devices for use in obese patients, "[W]here obesity is defined as three times normal body weight."

45. Prior to April of 2010, Wright did not state in its IFUs distributed in the United States a warning, precaution, or other advisory or information as to the use of its long modular necks in people who weighed more than a specifically stated weight.

46. Prior to April of 2010, Wright did not state in its IFUs distributed in the United States that the use of its long modular necks was contraindicated in heavyweight males.

47. Prior to April of 2010, Wright did not state in its IFUs distributed in the United States that the use of its long modular necks was contraindicated in patients who engaged in heavy lifting.

48. Prior to April of 2010, Wright did not state in its IFUs distributed in the United States that the use of its long modular necks was contraindicated in patients who engaged in impact sports.

49. Even though some Wright IFUs for these devices in use prior to April of 2010 contained a section title, “Conditions presenting increased risk of failure include,” in that section of the IFU Wright did not state that patients weighing more than a certain weight, engaging in a high level of activity, engaging in heavy lifting, or engaging in impact sports, would be at an increased risk of failure (fracture) of the modular neck.

50. Even though some Wright IFUs for these devices in use prior to April of 2010 contained a section titled “Warning,” and a subsection within titled “Modular Necks,” within that subsection of the IFU Wright did not state that patients weighing more than a certain weight, engaging in a high level of activity, engaging in heavy lifting, or engaging in impact sports, would be at an increased risk of failure (fracture) of the modular neck.

51. Even though some Wright IFUs for these devices in use prior to August of 2010 contained a section titled “General Product Information,” that stated, “An

overweight or obese patient can produce high loads on the prostheses, which can lead to failure of the prosthesis,” and, “If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation or the device, or both,” Wright did not state that patients involved in an occupation or activity that included those activities created any higher risk of failure than would exist in any other design of artificial hip stem without a modular neck.

52. Wright did not change the language in its IFUs distributed in the United States related to its Profemur modular necks discussing the issue of any specific patient weight or activity levels as they may relate to modular neck fractures until April of 2010, if not later.

53. On or after August 25, 2009, Wright began distributing in the United States Profemur modular necks made of a cobalt chrome alloy.

54. Profemur modular necks distributed in the United States made of cobalt chrome, are made in the same twelve sizes, versions, and dimensions as the Profemur Ti6Al4V modular necks.

55. The Profemur cobalt chrome modular necks are less susceptible to micromotion and fretting corrosion than the otherwise identical model of Profemur Ti6Al4V modular necks.

56. After implantation, Profemur long cobalt chrome modular necks are less likely to fail (fracture) from cyclic loading and metal fatigue than the otherwise identical model of Profemur Ti6Al4V long modular necks.

57. The technology to make Profemur modular necks out of a cobalt chrome alloy, rather than the Ti6Al4V alloy, was technically feasible prior to the year 2001.

58. The production of Profemur modular necks out of a cobalt chrome alloy, rather than the Ti6Al4V alloy, does not significantly increase the cost of manufacture compared to and considering the overall cost of the hardware for a Wright Profemur total hip system.

59. The production of Profemur modular necks out of a cobalt chrome alloy, rather than the Ti6Al4V alloy, is not known to significantly increase the risk of failure of the hip arthroplasty from other known complications, such as aseptic loosening of the acetabular component.

60. Wright has never directly informed patients in the United States who received its Profemur Titanium long modular necks, and have not yet experienced a modular neck fracture, that these products have experienced higher than anticipated rates of failure due to fracture of the modular neck.

61. Wright has never directly informed patients in the United States who received its Profemur Titanium long modular necks, and have not yet experienced a modular neck fracture, that patients of higher weight and/or higher levels of activity may place them at an increased rate of failure due to fracture of their modular necks.

62. Wright has never directly requested surgeons in the United States who implanted its Profemur Titanium long modular necks to directly inform any patients who received these modular necks that patients of higher weight and/or higher levels of

activity may place them at an increased rate of failure due to fracture of their modular necks.

63. Patient testimonials that have from time to time appeared on the Wright Medical website available to physicians, patients, and the public from 2005 to the present, and/or that appeared in printed materials published by Wright from 2005 to the present, have made the representations that patients who received Wright artificial hips have already returned, or are about to return, to such activities as running, jogging, snow skiing, water skiing, marathon running, tennis, racquetball, golf, horseback riding, work that involved lifting and moving of heavy objects, active military duty in Iraq, karate, competitive wrestling, and competitive motocross racing, among other activities.

64. Patient testimonials that have from time to time appeared on the Wright Medical website, and in printed materials published by Wright from 2005 to the present, have been from men who received these devices and weighed in excess of 250 pounds.

65. In a “webinar” produced by Wright and intended to be viewed by orthopedic surgeons, Brad Penenberg, M.D., an orthopedic surgeon who was paid by Wright to train other orthopedic surgeons to use a technique promoted by Wright for implantation of the Profemur modular neck hip system, states that he does not place restrictions on his patients after they recovered from hip replacement surgery, and that they may return to activities and lifestyles that included tennis, horseback riding, and snow skiing.

Plaintiff’s Wright Medical Hip

66. On February 13, 2006, plaintiff Michael Szymanski had a Wright Medical artificial hip implanted in the left side of his body by Eric L. Hume, M.D. at Cooper University Hospital in Camden, New Jersey.

67. The surgeon who implanted the plaintiff's Wright Medical Profemur hip, did not violate any generally accepted standards of care in the field of orthopedic surgery in his care and treatment of the plaintiff in any of the following respects:

- a. In the care or treatment that he provided to the plaintiff Michael Szymanski prior to beginning Mr. Szymanski's hip implant surgery;
- b. In the information that he did or did not provide plaintiff Michael Szymanski prior to beginning Mr. Szymanski's hip implant surgery;
- c. In the selection of the Wright hip system, or any of its components, that were implanted in Mr. Szymanski;
- d. In the hip implant surgery he performed on Michael Szymanski;
- e. In the care or treatment that he provided to the plaintiff Michael Szymanski subsequent to Mr. Szymanski's hip implant surgery; and
- f. In the information that he did or did not provide plaintiff Michael Szymanski subsequent Mr. Szymanski's hip implant surgery.

68. Based upon the patient population that the defendants intended its Profemur hip systems to be implanted in, at the time of implantation with his Wright Medical hip system on February 13, 2006, plaintiff Michael Szymanski was an appropriate patient to be implanted with this hip system.

69. At the time of implantation of the plaintiff with his Wright Medical hip system on February 13, 2006, a person whose identity is unknown at this time (John Doe No. 1) was present in the operation suite. This person had been trained by Wright to be

knowledgeable about its Profemur hip products, and brought with him/her various Wright Profemur hip components, including an array of various Profemur (Ti6Al4V) modular necks, and instruments to be used by the surgeon for implantation.

70. At no time before or during the plaintiff's hip implantation surgery did the above identified person (Doe No. 1) suggest that the plaintiff was a person who was an inappropriate patient for implantation with a Wright Profemur hip system.

71. Before or during the course of the surgery the above-identified person (Doe No. 1) delivered to the plaintiff's orthopedic surgeon the specific Wright Profemur hip system components that were implanted in the plaintiff.

72. Before or during or after the surgery the above identified person (Doe No. 1) obtained certain information about the plaintiff, his surgery, and the devices implanted in the plaintiff, including but not limited to:

- a. The date of the surgery;
- b. The identity of the hospital where the implantation surgery was performed;
- c. The identity of the implanting surgeon;
- d. Labels that had accompanied and identified the devices implanted in the patient;
- e. Unique identifying information about each of the devices implanted in the patient such as Lot and Reference numbers;
- f. The name of the patient; and,
- g. The date of birth of the plaintiff.

73. During or after the surgery, the above identified person (Doe No. 1) delivered or caused to be delivered to one of the Wright defendants, some or all of the

information he obtained about the plaintiff, his surgery, and the devices implanted in the plaintiff, including but not limited to:

- a. The date of the surgery;
- b. The identity of the hospital where the implantation surgery was performed;
- c. The identity of the implanting surgeon;
- d. Labels that had accompanied and identified the devices implanted in the patient;
- e. Unique identifying information about each of the devices implanted in the patient such as Lot and Reference numbers;
- f. The name of the patient; and,
- g. The date of birth of the plaintiff.

74. The plaintiff Michael Szymanski's Wright hip consisted, in part, of the following specific devices and components:

- a. PROFEMUR Z STEM, REF. PHA0-0270, LOT 095267634;
- b. PROFEMUR NECK REF. PHA0-1204, LOT: U1088875, STRAIGHT, LONG;

75. The plaintiff's Wright Medical hip components were distributed and sold in the United States by the Wright defendants by virtue of one or more 510(k) Premarket Notification procedures filed with the United States Food and Drug Administration.

76. Subsequent to the date of implant, the plaintiff Michael Szymanski used his Wright Medical Hip in a normal and expected manner.

77. On May 5, 2010, the modular neck component of the plaintiff's Wright Medical Hip suddenly and catastrophically failed, breaking into two pieces.

78. On May 10, 2010, the plaintiff's Wright Medical hip was surgically removed from the plaintiff by Eric L. Hume, M.D., at Cooper University Hospital in Camden, New Jersey, in a surgical procedure commonly called a "revision."

79. In the revision surgery performed on the plaintiff Michael Szymanski on May 10, 2010, his operating surgeon found that the modular neck component had fractured, and a remnant of the fractured Profemur modular neck was lodged in the Profemur stem and could not be removed.

80. Because the Profemur stem was well fixed in the femur, an extended trochanteric osteotomy was required to remove the stem with the retained remnant of the fractured modular neck.

81. In the plaintiff's revision surgery the Profemur stem, Profemur modular neck, and femoral head were each removed and replaced.

Allegations of Defective Product

82. The Profemur Titanium long modular neck is designed in a way that after implantation in a patient it may be subjected to excessive micromotion and fretting corrosion, thereby increasing the potential for failure due to fracture of the modular neck at or near the neck-stem junction.

83. The Profemur Titanium long modular neck is manufactured in such a way that after implantation it is susceptible to metal fatigue, fracture, and premature failure.

84. The Profemur Titanium long modular neck is manufactured in such a way that after implantation it is susceptible to metal fatigue, fracture, and premature failure when being subjected to the normal and expected activities of daily living.

85. The Profemur Titanium long modular neck is not designed and manufactured to withstand the normal activities of daily living after implantation without premature failure from fatigue fractures.

86. The Profemur Titanium long modular neck is not designed and manufactured to withstand the normal activities of daily living after implantation in active or heavier weight patients without premature failure from fatigue fractures.

87. The Profemur Titanium long modular neck was not tested in design and development at the level of forces that were known would be encountered in the normal activities of daily living.

88. The Profemur Titanium long modular neck was not tested in design and development at the level of forces that were known would be encountered in the normal activities of daily living of active or heavier weight patients.

89. The Profemur Titanium long modular neck was not tested for the FDA Section 510(k) Premarket Notification Process at the level of forces that were known would be encountered in the normal activities of daily living.

90. The Profemur Titanium long modular neck was not tested for the FDA Section 510(k) Premarket Notification Process at the level of forces that were known would be encountered in the normal activities of daily living or active or heavier weight patients.

91. The Profemur Titanium long modular neck was not tested in design and development at the level of forces equal to the level of activities of patients that Wright promoted and marketed these devices to.

92. The Profemur Titanium long modular neck was not tested for the FDA Section 510(k) Premarket Notification Process at the forces equal to the level of activities of patients that Wright promoted and marketed these devices to.

93. The Profemur Titanium long modular neck was known by the Wright defendants to be failing from fatigue fractures of the modular necks prior to the date of its FDA Section 510(k) Premarket Notification application.

94. The Profemur Titanium long modular neck was known by the Wright defendants to be failing from fatigue fractures of the modular necks prior to December 13, 2000, the date it received permission from the FDA to distribute these devices in the United States.

95. The Profemur Titanium long modular neck was known by the Wright defendants to be failing at higher than expected rates from fatigue fractures of the modular necks prior to the date of its implantation in the plaintiff.

96. The Profemur Titanium long modular neck was known by the Wright defendants to be failing at higher than expected rates from fatigue fractures of the modular necks prior to May 5, 2010, the date it fractured in the plaintiff.

97. Prior to the implant of the Profemur Titanium long modular neck in the plaintiff, the Wright defendants did not warn patients, surgeons, customers, or its field representatives that the long neck component of these devices was known to be failing at higher than expected rates from fatigue fractures.

98. Prior to the implant of the Profemur Titanium long modular neck in the plaintiff, the Wright defendants did not warn patients, surgeons, customers, or its field

representatives that the long neck component of these devices was known to be failing at higher than expected rates from fatigue fractures in high activity or heavier weight patients.

99. Prior to the date of the sudden catastrophic failure of the plaintiff's Profemur modular neck, the Wright defendants did not warn patients that the Profemur Titanium long modular neck was known to be suddenly and catastrophically failing without warning from fatigue fractures during normal activities of daily living.

100. Prior to the date of the sudden catastrophic failure of the plaintiff's Profemur modular neck, the Wright defendants did not warn patients that the Profemur Titanium long modular neck was known to be suddenly and catastrophically failing without warning from fatigue fractures in high activity or heavier weight patients.

101. The Profemur Titanium long modular neck is of a design that it may suddenly and catastrophically fail when being used in accordance with the levels of activity and use that it was marketed and promoted for by the defendants Wright.

102. The Profemur Titanium long modular neck is of a design that it will fail by suddenly and catastrophically breaking into two pieces when being used in reasonable and foreseeable ways.

103. The Profemur Titanium long modular neck is of a design that it is not able to withstand the forces that it will be subjected to over time in the course of regular activities of daily living, and will suddenly, catastrophically, and without warning break into two pieces.

104. The Profemur Titanium long modular neck is of a design that it is susceptible to micromotion, and fretting corrosion, that may lead to it failing by suddenly and catastrophically breaking into two pieces when being used in reasonable and foreseeable ways.

105. The Profemur Titanium long modular neck is of a design that it is susceptible to imperfections and inconsistencies in manufacture that make it unpredictably weak in spots, and therefore more susceptible to metal fatigue, and sudden and catastrophic failure by breaking in two.

106. The Wright Medical hip system with the Profemur Titanium long modular neck was marketed and promoted by the Wright defendants and their trained representatives for uses, longevity, and durability that exceeded its design, capabilities, and limitations known to Wright.

107. The Wright Medical hip system with the Profemur Titanium long modular neck was marketed and promoted by the Wright defendants and their trained representatives for uses, longevity, and durability that exceeded their design, capabilities, and limitations as stated in the IFUs that the Wright defendants published for these devices.

108. Prior to the date of implant in the plaintiff the Wright Medical hip system with the Profemur Titanium long modular neck were known by the Wright defendants to be failing from catastrophic failure of the long modular neck at a rate higher than expected by Wright.

109. Prior to the date of implant in the plaintiff the Wright Medical hip system with the Profemur Titanium long modular neck were known by the Wright defendants to be failing from catastrophic failure of the modular necks at a rate higher than the stem fracture rate of other comparable artificial hip systems readily available on the market that did not employ a modular neck design.

110. Prior to the date of implant in the plaintiff the Wright Medical hip system with the Profemur Titanium long modular neck were known by the Wright defendants to be failing from catastrophic failure of the modular necks at a rate higher than other comparable modular stem artificial hip systems readily available on the market that did not have a modular neck design at the point where the femoral neck meets the femoral stem.

111. Prior to the date of implant in the plaintiff the Wright defendants did not warn patients, surgeons, customers, or its field representatives that the Wright Medical hip system with the Profemur Titanium long modular neck were known to be failing from modular neck fractures at higher than expected rates.

112. Prior to the date of implant in the plaintiff the Wright defendants did not warn patients, surgeons, customers, or its field representatives that the Wright Medical hip system with the Profemur Titanium long modular neck were being revised at a rate higher than other comparable artificial hip systems readily on the market that did not employ a modular neck design.

113. Prior to the date of implant in the plaintiff the Wright defendants did not warn patients, surgeons, customers, or its field representatives that the femoral necks of

114. Prior to the date of implant in the plaintiff the Wright defendants did not warn patients, surgeons, customers, or its field representatives that higher patient weight, and higher levels of patient activity, placed a patient at a higher risk of the Profemur Titanium long modular neck fracturing.

115. The Wright Medical hip system with the Profemur Titanium long modular neck is designed, manufactured, labeled, marketed, and promoted in such a way that it fails by modular neck fracture and needs to be surgically revised in substantially less time than other comparable devices readily available on the market.

116. The Wright Medical hip system with the Profemur Titanium long modular neck is designed, manufactured, labeled, marketed, and promoted in such a way that it has a substantially higher rate of failure by modular neck fracture than other comparable devices readily available on the market.

117. After the Wright defendants received notice that the Profemur Titanium long modular necks were failing from neck fractures at higher than expected rates, and at rates higher than other comparable hip systems, they did not timely disclose that information to patients or surgeons.

118. After the Wright defendants received notice that the Wright Medical hip system with the Profemur Titanium long modular neck were failing from modular neck fractures at higher than expected rates, and at rates higher than other comparable hip

systems, they continued to market, distribute, and sell these devices to hospitals, surgeons, patients and other customers and consumers.

119. Defendants, John Doe Individuals 1-5 were responsible in some manner for the events and happenings referred to herein and negligently or otherwise caused the injuries or damages as alleged in this Complaint.

120. Defendants, John Doe Corporations 6-10 were negligent and/or otherwise responsible in some manner for the events and happenings referred to herein and negligently or otherwise caused the injuries or damages as alleged in this Complaint.

FIRST CAUSE OF ACTION

NEW JERSEY PRODUCT LIABILITY
(N.J. Stat. Ann. §2A:58C-1 et. seq)

Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

121. The defendants Wright manufactured, sold, distributed, marketed, promoted and/or supplied its Profemur hip system in general, and the Profemur titanium modular neck specifically, which was expected to reach and did reach consumers, including plaintiff, Michael Syzmanski, without substantial change in the condition in which it was manufactured and sold by defendants.

122. The defendants' Profemur hip system in general, and the Profemur titanium modular neck specifically, was expected to and did reach consumers, including plaintiff, Michael Szymanski, without substantial change in the condition in which it was manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

123. Plaintiff, Michael Szymanski used the defendants' Profemur hip system general and the Profemur titanium modular neck as prescribed and in a manner normally intended, recommended, promoted, and marketed by defendants.

124. The defendants' Profemur hip system in general, and the Profemur titanium modular neck specifically, failed to perform safely when used by ordinary consumers, including plaintiff, Michael Szymanski, even when used in its intended or a reasonably foreseeable manner.

125. The defendants' Profemur titanium long modular neck was defective in its design and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design.

126. The defendants' Profemur hip system with a Profemur titanium long modular neck is defective in design in that it poses a greater likelihood of injury than other artificial hip systems on the market and is more dangerous than ordinary consumers can reasonably foresee.

127. Although defendants knew, or should have known, of the defective nature of the defendants' Profemur titanium long modular neck, they continued to design, manufacture, market and sell Profemur titanium Ion modular necks for implantation in patients in the United States so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious and deliberate disregard of the foreseeable harm caused by these devices.

128. Plaintiff, Michael Szymanski, could not, through the exercise of reasonable care, have discovered the defects or perceived the danger of the defendants' Profemur titanium long modular neck implanted in his hip as a component of his Profemur hip system.

129. Based upon all of the claims and allegations set forth above, the plaintiff Michael Szymanski's Wright Medical hip system with the Profemur titanium long modular neck was designed, manufactured, labeled, marketed, distributed, sold, supplied and/or placed into the stream of commerce by the defendants Wright, was defective and unreasonably dangerous in its design, manufacture, and/or labeling when it left the hands of the defendants Wright.

130. Based upon the allegations set forth above, the plaintiff's Wright Medical hip system with the Profemur titanium long modular neck was defective in design, manufacture, and had inadequate warnings.

131. Based upon the allegations set forth above, the defective condition of the plaintiff's Wright Medical hip system with the Profemur titanium long modular neck rendered the product unreasonably dangerous.

132. Based upon the allegations set forth above, the defective condition of the plaintiff's Wright Medical hip system with the Profemur titanium long modular neck existed when the product left the manufacturer's control.

133. Based upon the allegations set forth above, the defective condition of the plaintiff's Wright Medical hip system with the Profemur titanium long modular neck existed when the product reached the user, the plaintiff, without substantial change.

134. Based upon the allegations set forth above, the defective condition of the plaintiff's Wright Medical hip system with the Profemur titanium long modular neck was a proximate cause of the plaintiff's damages.

135. The Wright Medical hip system with the Profemur titanium long modular neck and its components that were implanted in the plaintiff were and are unreasonably dangerous for their intended and/or reasonably foreseeable uses in that:

- A. They were and are unreasonably dangerous under the risk-utility test as a result of one or more, or a combination of, the following conditions:
 - (1) The modular neck component was insufficient to withstand without fracturing the forces that it was reasonably expected to be subjected to in activities of daily living;

- (2) There were safer alternative substitute devices available on the market;
- (3) There were safer alternative designs that were reasonably feasible in both engineering and materials, that would not have substantially increased the cost, and that did not materially increase any other risks of use;
- (4) Wright had the ability to eliminate the unsafe characteristic without great expense or impairing its usefulness by manufacturing the modular neck out of a readily available cobalt chrome alloy, instead of the Ti6Al4V titanium alloy;
- (5) The Wright defendants promoted these hip devices with testimonials of patients who lived active lifestyles after being implanted with them while the devices it was promoting in these testimonials were not designed to withstand those types of activities without placing the patient at risk of fracture of the device;
- (6) The users, such as the plaintiff, could not have avoided the danger because the risk of sudden fracture without warning existed even in normal activities of daily living;
- (7) The users, such as the plaintiff, were not aware of the danger because the Wright defendants did not directly notify or warn the users that there was an increased risk of fracture even in normal activities of daily living;
- (8) The users, such as the plaintiff, were not aware of the danger because the Wright defendants did not adequately warn the learned intermediaries that there was an increased risk of fracture even in normal activities of daily living;
- (9) A practical and feasible, safer, alternative design existed that would have reduced or prevented the risk of fracture under normal expected activities;
- (10) The warnings or instructions were inadequate under N.J. Stat. Ann. §2A:58C-4, in they were not instructions or warnings that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicated adequate information on the dangers and safe use of the product, taking into account the

characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used;

- (11) The Wright defendants did not warn patients, surgeons, customers, or its filed representatives that these devices were known to be failing from modular neck fractures at higher than expected rates prior to the date of implant in the plaintiff; and
 - (12) Once failures by fracture were known to be occurring, the Wright defendants did not warn patients, nor the plaintiff in particular, that these devices were known to be failing from modular neck fractures at higher than expected rates prior to the date of plaintiff's failure.
- B. They were and are dangerous to an extent beyond which would be contemplated by the ordinary consumer with the ordinary knowledge common to the community as to its characteristics in that:
- (1) The ordinary patient consumer would not expect that the Wright Medical Profemur hip system would fail from normal activities of daily living by fracture of the modular neck at all, no less than in less than five years after implantation;
 - (2) The ordinary patient consumer would not expect that the Wright Medical hip system would fail by fracture of the device from engaging in activities that were promoted by Wright as within the expectations of the device.
 - (3) The ordinary learned intermediary consumer would not expect that the Wright Medical Profemur hip system would fail from normal activities of daily living by fracture of the modular neck at all, no less than in less than five years after implantation; and
 - (4) The ordinary learned intermediary consumer would not expect that the Wright Medical hip system would fail by fracture of the device from engaging in activities that were promoted by Wright as within the expectations of the device.

136. Based upon the allegations set forth above, the plaintiff's Wright Medical hip with the Profemur titanium long modular neck was defective in that it was dangerous beyond that which would be contemplated by the ordinary patient consumer who purchased it, with the ordinary knowledge common to the community as to its characteristics.

137. Based upon the allegations set forth above, the plaintiff's Wright Medical hip with the Profemur titanium long modular neck was defective in that it was dangerous beyond that which would be contemplated by the ordinary learned intermediary consumer who purchased it, with the ordinary knowledge common to the community as to its characteristics.

138. Based upon the allegations set forth above, the plaintiff's Wright Medical hip with the Profemur titanium long modular neck was defective in design in that the harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer, and the omission of that alternative design rendered this product not reasonably safe.

139. Defendants' acts and omissions breached implied warranties of fitness and merchantability of the product supplied to and implanted in Plaintiff, Michael Szymanski.

140. As a direct result of Defendants' acts and omissions, as described herein, Plaintiff, Michael Szymanski was caused physical injury, and shall in the future be caused to suffer severe personal injuries, pain and suffering, severe emotional stress and

harm, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.

141. The conduct, actions and inactions of the defendants Wright, as set forth above and incorporated herein, demonstrates that the defendants Wright are strictly liable to the plaintiffs for their injuries and damages.

SECOND CAUSE OF ACTION

NEGLIGENCE

Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

142. The conduct, actions and inactions of the defendants Wright, as set forth above and incorporated herein, demonstrates that the defendants Wright failed to exercise ordinary and reasonable care in the design, manufacture, labeling, promotion, marketing, sale, testing, quality assurance, quality control, and distribution of the plaintiff's Wright Medical hip system in general, and specifically the Profemur Titanium modular neck used in that system.

143. The conduct, actions, and inactions of the defendants Wright, as set forth above and incorporated herein, were negligent.

THIRD CAUSE OF ACTION

RESPONDEAT SUPERIOR

144. Plaintiff incorporates the above averments by reference as if set forth fully at length herein.

145. At all relevant times, John Doe individuals (1-5) were employees, agents, or servants of Defendants and/or John Doe Corporations 6-10.

146. The business entity or corporate Defendants are responsible or vicariously liable for the negligence, acts and omissions of their agents, employees, and servants based on the theory of respondeat superior.

147. As a direct result of Defendants' acts and omissions, as described herein, Plaintiff, Michael Szymanski, was caused physical injury and shall in the future be caused to suffer severe personal injuries, pain and suffering, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages, and other damages.

FOURTH CAUSE OF ACTION

LOSS OF CONSORTIUM

148. Plaintiffs incorporate the above averments by reference as if set forth fully at length here.

149. Plaintiff, Kari Szymanski, is the wife of Plaintiff, Michael Szymanski, and is entitled to his care, comfort, companionship, services and consortium.

150. 116. As a direct and proximate result of the negligence of the Defendants herein, Kari Szymanski has been and will be deprived of the care, comfort, companionship, services and consortium of her spouse Michael Szymanski.

151. Wherefore, Plaintiffs demand judgment against Defendants for such sums in excess of \$75,000.00 for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the court deems proper.

FIFTH CAUSE OF ACTION

PUNITIVE CONDUCT

152. The conduct, actions and inactions of the defendants Wright, as set forth above, is clear and convincing evidence that the Wright defendants knowingly withheld or misrepresented to the United States Food and Drug Administration, material, and relevant information required to be submitted under the FDA's regulations.

153. The conduct, actions and inactions of the defendants Wright, as set forth above, is clear and convincing evidence of wanton and willful disregard by the Wright defendants of the health and safety of persons such as the plaintiff Michael Szymanski who foreseeably might be, and in fact was, harmed by that conduct.

DAMAGES FOR ALL CAUSES OF ACTION

Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and for their damages for each cause of action further allege as follows:

154. As a direct and proximate result of the failure of the Wright Medical hip, and the conduct, actions, inactions, omissions and negligence of the Wright defendants, the plaintiff Michael Szymanski has sustained injuries and damages including, but not limited to:

- a. Serious and permanent physical injuries to bone, muscle, tendons, and nerves in and around his hip and pelvis;
- b. Undergoing surgery to remove and replace the failed components and repair the damage that failure caused;
- c. Past and future pain, suffering, and anguish, both in mind and in body;
- d. Physical disability, past and future;
- e. Physical impairment;

- f. Disfigurement;
- g. Loss of enjoyment of life;
- h. Medical bills associated with the replacement surgery, therapy, and recovery there from;
- i. Future medical bills and expenses;
- j. Loss of past and future income and earning capacity, past and future; and
- k. Punitive damages in the maximum amount as allowed by New Jersey law.

155. As a direct and proximate result of the failure of the Wright Medical hip, and the conduct, actions, inactions and omissions of the Wright defendants, the plaintiff Kari Szymanski has sustained injuries and damages in the form of her loss of consortium with her husband, the plaintiff Michael Szymanski.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Michael Szymanski prays for an award of damages in excess of the jurisdictional amount of this Court against the defendants Wright Medical Group, Inc., Wright Medical Technology, Inc., and Wright Medical Europe S.A., jointly and severally, as follows:

- a. All economic, special, and compensatory damages, past and future, recoverable by the plaintiff under New Jersey law;
- b. All non-economic and general damages, past and future, recoverable by the plaintiff under New Jersey law;
- c. Punitive damages in the maximum amount as allowed by New Jersey law;
- d. Prejudgment and post-judgment interest;

- e. Costs as permitted by the Court to the prevailing party; and
- f. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

Plaintiff Kari Szymanski prays for an award of damages in excess of the jurisdictional amount of this Court against the defendants Wright Medical Group, Inc., Wright Medical Technology, Inc., and Wright Medical Europe S.A., jointly and severally, for her loss of consortium.

Respectfully submitted,

/s/ Thomas R. Anapol

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JURY TRIAL DEMANDED

Plaintiffs Michael Szymanski and Kari Szymanski hereby demand a trial by jury as to all issues in the above matter.

DATED this 26th day of April 2012.

Respectfully submitted,

/s/ Thomas R. Anapol

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